



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0010]

Cooperative Agreement to Support the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single-source application for the award of a cooperative agreement in fiscal year 2013 (FY13) to the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station Poultry Unit located in Salisbury, NC. Egg-associated illness due to Salmonella is a major public health concern, with table eggs being the primary source of Salmonella Enteritidis. Therefore, an FDA priority is to implement preventative measures to reduce the vertical and horizontal transmission of Salmonella Enteritidis and other Salmonella serovars to table eggs and poultry products. The goal of this collaborative project between FDA and the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station is to utilize a commercial research facility to parallel the transmission (vertical and horizontal) of Salmonella found within the egg-production industry and how alterations in physical feed characteristics and housing may influence vertical and horizontal transmission. Additionally, this study aims to examine how commercially utilized disinfection protocols affect horizontal transmission of Salmonella in alternative versus traditionally housed layer hens. Moreover, this study may reveal other serovars of Salmonella present within the

commercial egg industry which may pose a potential health risk to consumers. While historically the concern over Salmonella has focused on Salmonella Enteritidis, there is a potential concern that other Salmonella serovars could be a source for egg-transmitted human salmonellosis. Hence, this study aims to investigate the occurrence, transmission, and virulence of varying Salmonella serovars.

DATES: Important dates are as follows:

1. The application due date is July 15, 2013.
2. The anticipated start date is September 2013.
3. The expiration date is July 16, 2013.

ADDRESSES: Submit electronic applications to: <http://www.grants.gov>. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT:

Scientific/Programmatic Contact: Ondulla Toomer, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 8301 Muirkirk Rd., MOD-1 (HFS-025), Laurel, MD 20708, 240-402-3430, email: ondulla.toomer@fda.hhs.gov.

Grants Management Contact: Kimberly Pendleton Chew, Office of Acquisitions and Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2105 (HFA 500), Rockville, MD 20857, 301-827-9363, email: kimberly.pendleton@fda.hhs.gov.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at www.fda.gov/food/newsevents/default.htm.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-13-031

93.103

A. Background

Egg-associated illness due to Salmonella is a major public health concern, with table eggs being the primary source of Salmonella Enteritidis. Infected individuals may suffer gastrointestinal distress, short-term or chronic arthritis, or even death.

Salmonella Enteritidis is transmitted vertically (due to bacterial infection of the reproductive organs infecting the yolk, albumen, and/or membranes) or horizontally (due to microbial contamination post-oviposition from environmental or cloacal contamination). Upon the horizontal transmission of Salmonella, the micro-organism penetrates the eggshell infecting the yolk, albumen, and egg membranes. Therefore, an FDA priority is to implement preventative measures to reduce the vertical and horizontal transmission of Salmonella Enteritidis and potentially other Salmonella serovars to table eggs and poultry products (tissues). Intensive genetic selection for enhanced egg production has altered the ability to resist microbial contamination within laying hen breeders. Thus, it is imperative that interventional strategies be studied to ensure the safety of egg and poultry products for consumption.

Various studies (Bjerrum et al., 2005; Huang et al., 2006, Santos, 2006) have demonstrated that increasing the grain particle size in the diet reduced the vertical transmission of Salmonella. Bjerrum et al. (2005) reported that broilers fed a finely ground pelleted corn diet had a higher Salmonella population in the gizzard than broilers fed a coarsely ground corn pelleted diet. In parallel, Huang et al. (2006) reported a higher incidence of Salmonella

Typhimurium in the gizzard and cecal contents of broilers fed a finely ground corn pelleted diet, suggesting that feed structure may influence Salmonella colonization by altering the gastrointestinal microenvironment.

B. Research Objectives

Research objectives include utilizing a commercial research facility to parallel the transmission (vertical and horizontal) of Salmonella found within the egg production industry; indicating how alterations in physical feed characteristics and housing (traditional caging versus free-range) may influence vertical and horizontal transmission; and examining how commercially utilized disinfection protocols affect horizontal transmission of Salmonella in free-range versus traditionally housed layer hens. All research and microbiological analysis will be conducted at facilities housed at North Carolina State University, Prestage Department of Poultry Science and Piedmont Research Station, Salisbury, NC, using North Carolina State University Institutional Animal Care and Use Committee (IACUC) approved protocol #11-024-A. This cooperative agreement will provide support for collaborative research conducted between FDA-CFSAN-OARSA-Immunobiology and North Carolina State University, Prestage Department of Poultry Science utilizing the commercial research facility Piedmont Research Station to meet the following projected milestones:

1. Assess the routes of Salmonella transmission to eggs, egg and poultry products (tissues), and examine tissue colonization.
2. Assess the immunological responses of the layer hen to Salmonella challenge post- and pre-molting.
3. Examine the prevalence of differing Salmonella serovars in various environmental layer hen housing systems (conventional cage, enriched cage systems, and free-range).

4. Examine the effect of various nutritional intervention strategies (physical feed characteristics, antimicrobials, immuno-enhancing feed ingredients) on vertical transmission rates in a commercial-style environment.
5. Examine the use of differing disinfection protocols on the rates of horizontal transmission in various environmental layer hen housing systems (conventional cage, enriched cage systems, and free-range).

C. Eligibility Information

Competition is limited to the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station because FDA finds that the North Carolina State University Department of Poultry Science and the Piedmont Research Station are uniquely qualified to fulfill the objectives outlined in the proposed cooperative agreement.

The goal of this collaborative project is to utilize a commercial research facility to parallel the transmission (vertical and horizontal) of Salmonella found within the egg production industry and how alterations in physical feed characteristics and housing may influence vertical and horizontal transmission.

The Piedmont Research Station Poultry Unit is a unique facility that has housing for over 15,000 commercial layers, 8,000 broiler breeders, and incubation capacity to hatch more than 52,000 eggs at one time utilizing both multistage and single-stage incubation. The Prestage Department of Poultry Science Research and Teaching Units in Raleigh, NC conduct research at the Piedmont Research Station. Research at both unit locations includes commercial layers, commercial broiler breeders, broilers, and commercial-style incubation. Piedmont Research Station routinely conducts the Layer Performance Management Test in North America, with studies in applied production practices and nutrition management. These facilities are able to

evaluate the effects of a research project on a size and scale that mimics commercial poultry operations.

The North Carolina State University feed mill is a research and educational feed mill that is designed and equipped to manufacture a variety of feed mix characteristics, formulations, and feed forms. It is currently used by FDA for training purposes associated with the safe feed-safe food program, and is among the few research feed mills in the country that is associated with animal research facilities. The mill has all of the typical process equipment found in commercial feed mills, including an 8 ton/hr CPM hammer mill, 8 ton/hr RMS roller mill, micro bin-batching system, a 500 lb horizontal ribbon mixer, a 2 ton double-shaft ribbon mixer, a 1 ton/hr CPM pellet mill with counter-flow cooler, a 10 ton/hr Bliss pellet mill with counter-flow cooler, pellet screener, bagger, bulk ingredient bins, finished feed bins, and an automated computer-controlled batch mixing and process operation. This feed mill is able to manufacture feed of various feed ingredient grind size in mash or pellet forms.

While other academic institutions also have outstanding poultry and egg research programs, they do not have commercial style research facilities, feed mill, and resources to conduct large-scale commercial size research projects. Moreover, the North Carolina State University, Prestage Department of Poultry Science and Piedmont Research Facility are within close geographic proximity for collaboration with FDA's Department of Immunobiology. This will allow FDA's investigational scientists to travel by automobile on key experimental dates to initiate research experiments and to collect tissue and environmental samples. These samples will be transported within 24 hours back to FDA's Department of Immunobiology for microbiological testing and analysis.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) intends to fund one award up to \$50,000 total costs (direct plus indirect costs) for FY 2013. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support and include future recommended support for 4 additional years, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at www.fda.gov/food/newsevents/default.htm. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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